

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO: <i>Paula Houck, et al. v. Ethicon, Inc., et al.</i> Case No. 2:12-cv-08091	

**MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS’ MOTION TO LIMIT THE CASE-SPECIFIC
OPINIONS AND TESTIMONY OF DR. DANIEL ELLIOTT, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, “Ethicon”), submit this Memorandum of Law in Support of Defendants’ Motion to Limit the Case-Specific Opinions and Testimony of Dr. Daniel Elliott, M.D., pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny.

The Court should limit or exclude his case-specific opinions to the extent such opinions are predicated upon his inadmissible general causation opinions. Additionally, the Court should exclude the following case-specific opinions offered by Dr. Elliott: (1) opinions concerning warnings (including the informed consent process) because such opinions do not fit the facts of this case; and (2) “quality of life” opinions because such opinions are not helpful to the jury and Dr. Elliott lacks the qualifications to opine on psychological and emotional damages.

I. Background

On June 3, 2009, Plaintiff Paula Houck underwent surgical implantation of TVT-O performed by Dr. Daniel Kim for the treatment of stress urinary incontinence. Ex. A, Expert Case Specific Report of Ms. Paula Houck by Dr. Daniel Elliott [“Case-Specific Report”] at 36–37. Dr.

Kim performed concomitant laparoscopic lysis of adhesions, bilateral salpingo-oophorectomy, native-tissue anterior and posterior colporrhaphy, and cystoscopy with hydrodistention to address preoperative diagnoses of pelvic pain, cystocele, rectocele and interstitial cystitis. *Id.* Since that time, Ms. Houck has undergone two procedures to remove exposed mesh; a sling urethropexy with a cadaveric pubovaginal sling, urethral lysis and vaginal reconstruction to address recurrent incontinence, pain with intercourse and narrow vaginal canal; and a urethrolysis to release the pubovaginal sling due to urinary retention. *Id.* at 38–43.

Plaintiffs have designated Dr. Daniel Elliott as an expert urologist offering opinions as to both general and “case-specific” causation. Ex. B, Pl.’s Designation and Disclosure of Case-Specific Expert Witnesses at 1–2. In the first 33½ pages of his 46-page “case-specific” report, Dr. Elliott offers various general opinions concerning alleged defects and mistakes in the design, testing, premarket clearance, warnings, and instructions for the TVT-O device. *See* Ex. A, Case-Specific Report at 1–34.

Specific to Ms. Houck, Dr. Elliott opines that she has suffered extensive scarring, which led to vaginal pain and dyspareunia, and that this scarring led to the development of pelvic floor myalgia, which also causes pain and discomfort. *Id.* at 45. Further, Dr. Elliott opines that the TVT-O “has caused a severe compromise to Ms. Houck’s quality of life,” and that “the long-term negative impact on her quality of life” could lead to “feelings of isolation, loneliness, depression and suicide.” *Id.* at 45–46. He also opines that Ms. Houck was unable to render “a fully informed medical decision regarding the implantation of the TVT-O polypropylene mesh because Ethicon failed to fully disclose the risks, complications (both early and late), and the consequences thereof, in Ethicon’s Instructions for Use.” *Id.* at 46.

II. Legal Standard

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *1–3 (S.D. W. Va. July 8, 2014).

III. Argument

A. Dr. Elliott’s Case-Specific Opinions Should Be Limited or Excluded to the Extent Such Opinions are Predicated Upon His Inadmissible General Causation Opinions.

Dr. Elliott’s general TVT-O opinions set forth in his “case-specific” report for Ms. Houck are inadmissible for many of the same reasons as his general opinions regarding TVT-O and other products, as disclosed in other Wave cases. For example, Dr. Elliott opines that the polypropylene mesh in TVT-O degrades, leading to clinical complications; that Ethicon “downplayed” adverse risks and complications in the applicable Instructions for Use (“IFU”); and that Ethicon did not conduct adequate testing or studies regarding the TVT-O. Ex. A, Case-Specific Report at 4. Throughout the first 33½ pages of his “case-specific” report, Dr. Elliott offers opinions regarding what Ethicon “knew” and when Ethicon knew it. *See id.* at 1–34.

However, this Court has previously excluded Dr. Elliott’s opinions regarding marketing and Ethicon’s “state of mind” and corporate conduct, (*see* Mem. Op. & Order, No. 2:13-cv-22473, Doc. No. 265, at 17–26); his opinions linking degradation to clinical harm, *see In Re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Lit.*, 2016 WL 4500768, at *3 (S.D. W. Va. Aug. 26, 2016); as well as his “warnings” opinions (*see* Order Adopting Mem. Op & Order, No. 2:12-md-02327, Doc. No. 6409, at 2 (S.D. W. Va. July 27, 2018)). As such, Dr. Elliott’s case-specific opinions regarding Ms. Houck should be limited or excluded to the extent such opinions are predicated upon his inadmissible general causation opinions, including the general opinions recited in his “case-specific” report. *See, e.g., In re C.R. Bard*, 948 F. Supp. 2d 589, 605 (S.D. W. Va. 2013) (noting

that “establishing general causation is an essential prerequisite to proving specific causation”) (internal citations omitted).

B. This Court Should Exclude Dr. Elliott’s Opinions on Warnings and Informed Consent.

Although couched in terms of “informed consent,” Dr. Elliott offers the opinion that the TVT-O warnings were inadequate. Ex. A, Case-Specific Report at 46. Similarly, the general section of Dr. Elliott’s “case-specific” report contains numerous references to the inadequacy of the warnings for TVT-O. *See, e.g., id.* at 29–31. For the reasons set forth below, the Court should exclude these opinions.

1. Dr. Elliott is not qualified to offer opinions regarding what should or should not be included in an IFU.

Dr. Elliott opines that Ms. Houck was unable to make an informed medical decision because Ethicon “failed to fully disclose the risks, complications (both early and late), and the consequences thereof” in its IFU for TVT-O. Ex. A, Case-Specific Report at 46. Stated differently, Dr. Elliott is offering the opinion that Ethicon should have, but did not, include certain information in the TVT-O IFU.

As noted above, this Court has previously held that Dr. Elliott is not qualified to offer opinions about what should or should not be included in a particular product’s IFU. *See* Order Adopting Mem. Op & Order, No. 2:12-md-02327, Doc. No. 6409, at 2 (S.D. W. Va. July 27, 2018). Yet, that is precisely what he has done here. Therefore, Dr. Elliott’s case-specific warnings opinions should be excluded for the same reasons that his general warnings opinions have been excluded.

2. Dr. Elliott's warnings opinions do not fit the facts of this case.

Dr. Elliott's case-specific warnings opinions should be excluded for the additional reason that such opinions (including any opinions about the adequacy of the informed consent process) do not fit the facts of this case.

Federal Rule of Evidence 702 requires that an expert opinion be "based on sufficient facts or data," and that the expert "reliably appl[y] the principles and methods to *the facts of the case*." Fed. R. Evid. 702 (emphasis added). In other words, to be admissible, Dr. Elliott's opinions must have some basis in the record. *See Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999); *Tyger Constr. Co. v. Pensacola Constr. Co.*, 29 F.3d 137, 142 (4th Cir. 1994) ("An expert's opinion should be excluded when it is based on assumptions which are speculative and are not supported by the record."). Expert testimony that is not based on the record "offers no assistance to the trier of fact in understanding the evidence because it lacks an adequate foundation in the evidence of the case." *Harrison v. United States*, No. 2:07-00696, 2009 WL 36545, at *7 (S.D. W. Va. Jan. 6, 2009); *see also Sparks v. Gilley Trucking Co.*, 992 F.2d 50, 54 (4th Cir. 1993) ("[A] court may refuse to allow a generally qualified expert to testify if his factual assumptions are not supported by the evidence.").

Under Maryland law, to establish a claim for failure to warn, a plaintiff must establish that (1) the defendant owed a duty to warn, (2) the defendant breached that duty, (3) there was a direct causal connection between the defendant's failure to warn and the alleged injuries, and (4) the plaintiff was harmed. *Higgins v. Diversey Corp.*, 998 F. Supp. 598, 604 (D. Md. 1997) (citing *Mazda Motor of Am. v. Rogowski*, 659 A.2d 391, 394-96 (Md. Ct. Spec. App. 1995)). As such, in order for Dr. Elliott's case-specific warnings opinions to be relevant to the issue of specific causation, the allegedly inadequate warnings must have directly caused Ms. Houck's injuries.

Dr. Elliott opines that Ms. Houck experienced extensive scarring, which led to vaginal pain and dyspareunia, which “likely contributed to the development of pelvic floor myalgia, which generates pain and discomfort as well.” *See* Ex. A, Case-Specific Report at 45. Dr. Elliott’s warnings opinions do not fit the facts of this case because, in fact, Ethicon expressly warned of the risks of scarring, pain and dyspareunia—the precise complications allegedly experienced by Ms. Houck as a result of the implantation of TVT-O. *See* Ex. C, 2008 TVT Brochure (warning of risks, including, but not limited to, difficulty urinating, **pain, scarring, pain with intercourse**, and mesh exposure that may require treatment) (emphasis added); Ex. D, TVT Surgeon Resource Monograph (warning of complications, including, but not limited to, bleeding, urinary retention, injury to the bladder/bowel/urethra, urethral erosion, mesh protrusion (or defective healing), de novo urge, infection of the mesh, and TVT device failure); Ex. E, TVT-O IFU (2009) (warning of foreign body response that could result in extrusion, erosion, fistula formation or inflammation).

Clearly, if Ethicon warned of the risk of the complications that Dr. Elliott opines were experienced by Ms. Houck, then there is no causal connection between Ethicon’s warnings and Ms. Houck’s injuries, and Dr. Elliott’s warnings opinions are irrelevant and do not fit the facts of this case.

Additionally, Dr. Elliott’s warnings opinions ignore the sworn testimony of Ms. Houck’s implanting physician, Dr. Kim. Specifically, Dr. Kim testified that he was aware of the risks associated with TVT-O long before Ms. Houck’s surgery in 2009—including the risks of pain, scarring, and pain with intercourse—and that such complications could be temporary or chronic and could necessitate additional procedures. *See* Ex. F, Daniel Kim, M.D. Dep. Tr. 17:12–26:16, 142:3–145:22; 147:19–148:8. Additionally, although Dr. Elliott opines that Ms. Houck was not properly consented regarding the TVT-O because Ethicon failed to fully disclose the risks and

complications in the TVT-O IFU, Dr. Kim testified that he did not even use the IFU during the consenting process with Ms. Houck. *Id.* at 146:10–14.

Because Dr. Elliott’s warnings opinions are contrary to, and indeed ignore, the sworn testimony given by Dr. Kim in this case, such opinions do not fit the facts of this case and should be excluded.

C. Dr. Elliott’s Opinions Regarding Psychological Injuries and Ms. Houck’s Quality of Life Should Be Excluded.

Dr. Elliott opines that the TVT-O has caused “a severe compromise to Ms. Houck’s quality of life[]” due to the resulting “lack of physical intimacy[,]” and that studies show that “long-term negative impact” on one’s “quality of life” could lead to “feelings of isolation, loneliness, depression and suicide.” *See* Ex. A, Case-Specific Expert Report at 46. Dr. Elliott’s opinions regarding Ms. Houck’s “quality of life” and the potential future emotional injuries that could result should be excluded as not helpful to the jury and as beyond the scope of his qualifications.

1. Dr. Elliott’s “quality of life” opinions are not helpful to the jury.

Two prerequisites for the admissibility of expert testimony under Fed. R. Evid. 702 are that the testimony must (1) concern “scientific, technical, or other specialized knowledge,” and it must “aid the jury or other trier of fact to understand or resolve a fact at issue.” *Hines v. Wyeth*, No. 2:04-06920, 2011 WL 2680842, at *1 (S.D. W. Va. July 8, 2011) (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257 (4th Cir. 1999)). As such, “[e]xpert testimony which ‘merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness’ is properly excluded.” *In re C.R. Bard, Inc.*, 948 F.Supp.2d 589, 608 (S.D. W. Va. 2013) (quoting *Hines*, 2011 WL 2680842, at *5).

In *In re C.R. Bard, Inc.*, plaintiffs sought to admit expert testimony from “relationship experts” regarding the “impact of the bellwether plaintiffs’ loss in terms of body image, self-

esteem, confidence, sexual drive and the ability to maintain an affectionate sexual relationship[.],” as well as opinions regarding the plaintiffs’ “loss in terms of how and why the quality of their intimate relationships has changed, and what affect [sic] that has in terms of self-concept, connections and pain experienced as a result.” *Id.* at 607. This Court noted that portions of the experts’ reports “merely state what the plaintiffs told them,” and held that “[s]uch testimony is better presented directly to the jury via the . . . plaintiffs themselves.” *Id.* at 608. Further, this Court held that, even if the “relationship experts” “reliably applied scientific literature to the facts presented to them by the plaintiffs,” their opinions should be excluded because “expert testimony on this issue is unnecessary because it is understandable to the average juror.” *Id.*

Like the opinions of the “relationship experts” in *In re C.R. Bard, Inc.*, Dr. Elliott’s opinions regarding the loss of intimacy that she’s allegedly experienced as the result of her physical injuries, and any associated impact on her quality of life, relate to matters that are “understandable to the average juror” and, as such, Dr. Elliott’s “quality of life” opinions are not helpful to the jury and should be excluded.

2. Dr. Elliott’s is not qualified to offer his “quality of life” opinions.

Federal Rule of Evidence 702 provides that an expert may be qualified by “knowledge, skill, experience, training or education.” Dr. Elliott is a Professor of Urology specializing in treatment of pelvic organ prolapse and stress urinary incontinence in women and urinary incontinence in men. Ex. A, Case-Specific Report at 1. There is no indication that Dr. Elliott’s knowledge, skills, experience, training, or education qualify him to offer “quality of life” opinions or opinions regarding possible future emotional injuries. Consequently, he should be precluded from testifying at trial about mental illness, depression, anxiety, feelings of isolation, or suicide. *Id.* at 46.

IV. Conclusion

For the reasons stated above, this Court should limit or exclude Dr. Elliott's case-specific opinions as set forth herein.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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